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January 16, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1961
Rockville, MD 20852

Re: Docket No. 1998D-0834
Draft Guidance for Industry on
Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor
Symptoms and Vulvar and Vaginal Atrophy Symptoms-Recommended Prescribing
Information for Health Care Providers and Patient Labeling

Dear Sir/Madam:

Reference is made to the November 16, 2005 Federal Register Notice (FR Doc. 05-22754), which announced the availability of *Draft Guidance for Industry on Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms-Recommended Prescribing Information for Health Care Providers and Patient Labeling*.

The purpose of this submission is to provide the Agency with the following comments pertaining to the Draft Guidance, which would be applied to the labeling for all noncontraceptive estrogen drug products approved for the treatment of vasomotor symptoms and vulvar and vaginal atrophy symptoms (i.e., class labeling):

The final published reports from the estrogen-plus-progestin substudy of the Women's Health Initiative (WHI) study are based on centrally adjudicated data, which update the data from the estrogen-plus-progestin substudy initially published in JAMA in July 2002. It is Wyeth's recommendation that the data in the Draft Guidance presented in tabular format as "Relative and Absolute Risk Seen in the CE/MPA Substudy of WHI", beginning on page 8, line 279, be updated to reflect the current adjudicated data, which are considered the most scientifically valid data. The sentences preceding this table should also be updated to indicate that the data in this table are final results of the estrogen-plus-progestin substudy, which were centrally adjudicated after an average follow-up of 5.6 years. In addition, all other

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sections of the Draft Labeling Guidance, which reference data from the estrogen-plus-progestin substudy, should reference the updated adjudicated data accordingly. These data have been published by WHI investigators and can be found on the WHI website, www.whi.org.

Should you have any questions regarding this submission, please contact the undersigned at 484-865-3729 or Jennifer Norman at 484-865-3749.

Sincerely,



Caroline M. Henesey, Ph.D.
Director
Worldwide Regulatory Affairs